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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/476,630	06/07/95	DOBROGOSZ	W BIOA5063LBTG
EXAMINER			

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18M2/1001

MARY, I	
ART UNIT	PAPER NUMBER

1808

DATE MAILED: 10/01/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 6/18/97
- ☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 45-89 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 45-89 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The amendment filed July 30, 1997 is acknowledged. Claims 45-49 are being considered on the merits.

The rejection regarding double patenting is withdrawn in view of the proper terminal disclaimer provided.

Claims 45-46 are/remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

No basis or support is found in the as filed written disclosure for the use of 200 µg of β-hydroxypropionaldehyde per gram of food item to reduce the number of bacteria at least 10³ fold in a food item for animals..

No clear basis or support is found for a multi-log factor decrease in the number of any non-*Lactobacillus reuteri* bacteria in any substrate or any anaerobic environment merely if a 10-fold less than the number of bacteria present of *L. reuteri* is added and a stated concentration of glycerol or glyceraldehyde precursor is present. Moreover, the selection process for "a bacterial strain" raises the issue of new matter.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

It is noted that 100 units is equivalent to 200 µg β-glyceraldehyde. However, it is unclear that the results of page 20 pertain to the reduction of any and all bacteria in 3-6 days in the manner claimed. The results presented pertain to "indigenous population of bacteria" in ground

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meat stored at 4°C. In any case, no basis or support is found for the open ended “at least 10³-fold”.

Therefore the rejection is deemed proper and it is adhered to.

Claims 45-49 are/remain rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is vague and indefinite in that the antecedent basis for “said cells” is unclear in this context. Anaerobic storage encompasses food vacuum packed in a can or package, lyophilized items, frozen items, etc.. The scope of the claim cannot be assessed from the context presented.

Claim 47 is confusing, since it is unclear what the treatment is intended to be. There are “adding” steps. However it is unclear where this material is to be “added”, i.e., it is unclear where the treatment is to take place. Is “adding” a sufficient “treatment” for non-Lactobacillus reuteri bacteria” or is “contacting” required?. A culturing step appears to be missing. Is this an *in vitro* or an *in vivo* process? How is the determination of the number of bacteria in the composition to be treated or in the body carried out? How long is the treatment intended to be carried out? Growth and proliferation of bacteria takes time. However, a growth or incubation step is not included and a time frame not disclosed. Applicants have not provided an enabling disclosure for the treatment of any and all pathogenic bacteria that are non-*Lactobacillus reuteri* in any

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organism, including humans. As indicated in the last Office action, if an *in vitro* process is intended, this material should be clearly claim designated.

Claim 46 is vague and indefinite in that the phrase "A method for reducing the number of bacteria in a food item for animals" is not informative as to the material intended. The distinction in numbers reduced as compared with the control is also not understood. The terminology is ambiguous and open to interpretation. The nature of the bacteria to be reduced is unclear from the present context.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Regarding the Casas declaration, this declaration appears to be directed to specific animals, while the claims are not so limited. It is still unclear that a sufficient enabling disclosure is provided for the number of microorganism cells required to colonize the gastrointestinal tract of insects and protozoa, for example, or that the required glycerol or glyceraldehyde concentration will be available for the production of β -hydroxypropionaldehyde. The results presented in the specification and in the papers cited in the Response pertain to specific animals. The papers cited are not in conformity with MPEP 609. They were considered to the extent that they are discussed in applicants' arguments. In particular, results pertaining to glycerol human blood serum and in the GI tract are noted (Response, page 10). However this is not pertinent to all animals as claimed. Are specific animals, such as mammals intended?

Therefore the rejection is deemed proper and it is adhered to.

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Claims 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is vague and indefinite in the recitation of "significantly", It is unclear what the metes and bounds of "significantly" are in this context; the term "significantly" is ambiguous and open to interpretation. The nature of the bacteria to be reduced is unclear from the present context.

Claim 47 is vague and indefinite in that it requires selecting a bacterial strain which produces β -hydroxypropionaldehyde without identifying the species and later pertains to "said *L. reuteri*". The phrase "said *L. reuteri*" fails to find proper antecedent basis in the claim. It is recommended that in item (b), the phrase be amended to read --selecting an *L. reuteri* bacterial strain which produces...--.

In claim 48 it is recommended that --said selected-- be added before "*L. reuteri*" at line 4 to clarify the strain fed to the animal. It is also suggested that --as a probiotic-- be added at line 4, to clarify the correlation between the preamble directed to "providing a probiotic" and colonization of the gastrointestinal tract.

Claim 49 is vague and indefinite in that in claim 48 glycerol or glyceraldehyde are already present in the gastrointestinal tract. Thus, in claim 48 the required amount may already be present and claim 49 fails to further limit claim 48.

Therefore the rejection is deemed proper and it is adhered to.

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No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-0294.



Irene Marx
Primary Examiner
Art Unit 1808